FEB 1 8 2000

K994244

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Surgical Gowns

Manufacturer:	Allegiance Healthcare Corporation One Butterfield Trail El Paso, Texas 79906
Regulatory Affairs Contact:	Sharon Robbins 1500 Waukegan Road MPWM McGaw Park, IL 60085
Telephone:	(847) 785-3311
Date Summary Prepared:	September, 1999
Common Name:	Convertors® Surgical Gowns
Classification:	Class II per 21CFR § 878.4040
Predicate Device:	Isolyser Industries Enviroguard Surgeons Gowns.
Description:	The gowns are comprised of a single base layer of degradable spunlaced nonwoven fabric in gown configurations of unreinforced, fabric reinforced and poly-reinforced. The fabric reinforced gown contains an additional layer of spunlaced nonwoven fabric in the chest and sleeves area. The poly-reinforced gown contains an additional layer of polyolefin film in the chest and sleeves of the gown.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Surgical Gowns

Intended Use:	Surgical apparel are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material.
Substantial Equivalence:	The Convertors® Surgical gowns are substantially equivalent to the Isolyser Enviroguard gowns in that: - the intended use is the same - the performance attributes are similar
Summary of testing:	All materials used in the fabrication of this Convertors® Surgical gowns were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, sensitization, and primary skin irritation. These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2000

Ms. Sharon Robbins
Regulatory Affairs Manager
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787

Re: K994244
Trade Name: Convertors® Surgical Gowns
Regulatory Class: II
Product Code: KGO
Dated: December 14, 1999
Received: December 16, 1999

Dear Ms. Robbins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance

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510(k) Number (if known): Unknown K994244

Device Name: Convertors® Surgical Gowns, Sterile

Indications For Use: The Convertors® Surgical Gowns are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use ✓
(Per 21 CFR 801.109)

28

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994244